

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

Key Medical Supply, Inc.,
a Minnesota Corporation,

Civil No. 12-752 (DWF/JJG)

Plaintiff,

v.

**MEMORANDUM
OPINION AND ORDER**

Kathleen Sebelius, Secretary of the
United States Department of Health and
Human Services, in her official capacity;
and Marilyn Tavenner, Acting Administrator
of the Centers for Medicare and Medicaid
Services, in her official capacity,

Defendants.

Samuel D. Orbovich, Esq., and Lousene M. Hoppe, Esq., Fredrikson & Byron, PA,
counsel for Plaintiffs.

Friedrich A. P. Siekert, Assistant United States Attorney, United States Attorney's
Office; Clifford Lee Reeves, II, Esq., and Gregory Dworkowitz, Esq., United States
Department of Justice, counsel for Defendants.

INTRODUCTION

This matter is before the Court on Defendants' Motion to Dismiss for Lack of
Subject Matter Jurisdiction, or in the Alternative, Motion for Summary Judgment Based
on the Administrative Record (Doc. No. 29) and Plaintiff's Second Motion for
Temporary Restraining Order (Doc. No. 70). As stated in the Court's February 26, 2013

Order, and for the reasons set forth below, the Court grants Defendants' motion to dismiss and denies the remaining motions as moot.

BACKGROUND

I. Factual Allegations

Plaintiff is a vendor of medical supplies and equipment, including enteral nutritional supplies. (Compl. ¶¶ 11, 12.) Enteral nutrition refers to "tube feeding." In particular, Plaintiff supplies low-profile enteral gastric tubes, which are tubes that are custom-sized to fit each user's body.¹ (*Id.* ¶ 57.) Plaintiff provides equipment and supplies to patients who reside in their homes and are covered by insurance plans, including Medicare and Medicaid, and the Minnesota Home & Community Based Waiver Program. (*Id.* ¶¶ 12, 13.) A substantial percentage of Plaintiff's clientele are persons with developmental and other disabilities. (*Id.* ¶ 15.)

Defendant Kathleen Sebelius is the Secretary of the United States Department of Health and Human Services (the "Secretary"). (*Id.* ¶ 18.) In that capacity, the Secretary is charged with the responsibility to administer and oversee the Medicare and Medicaid programs. (*Id.*) The Secretary administers the Medicare and Medicaid programs through the Centers for Medicare and Medicaid Services ("CMS"). (*Id.*) Defendant Marilyn Tavenner is the Acting Administrator of CMS. (*Id.* ¶ 19.)

¹ Conventional tubes have long and protruding external tubes, which Plaintiff alleges are clinically inappropriate for some patients. (Compl. ¶¶ 51, 52.)

In this action, Plaintiff alleges that Defendants are implementing a Medicare competitive bidding program in a way that is inconsistent with their governing enabling legislation, the Medicare Prescription Drug Improvement Act of 2003, 42 U.S.C. § 1395w-3 (the “MMA”), and that Defendants’ current and historic fee for low-profile enteral gastric tubes, supplies, and nutritional formula is incompatible with Defendants’ competitive bidding program, such that no bona fide bid for these items is possible. (*Id.* ¶¶ 5, 6.) As a result, Plaintiff asserts that Defendants’ actions will end Plaintiff’s enteral-related Medicare business and its ability to provide low-profile feeding tubes and related supplies for its clients with developmental and other disabilities.² (*Id.* ¶ 8.)

In its Complaint, Plaintiff asserts the following causes of action: Counts One and Two—Violations of the Administrative Procedures Act, 5 U.S.C. §§ 701-606; Count Three—Violation of United States Constitution Takings Clause; Count Four—Violation of the United States Constitution Equal Protection Clause; Count Five—Violation of the United States Constitution Due Process Clause. (*Id.* ¶¶ 141-203.)

² Plaintiff asserts that Medicare will pay \$35.39 for each low-profile enteral tube, but that the approved amount is about 500%-937% below Plaintiff’s acquisition price for those products. (Doc. No. 6, Reinhart Decl. ¶¶ 7-8.) Plaintiff also asserts that Medicare will not pay additional amounts for the extension tubes needed to deliver the nutritional formula through the tubes and limits the number of reimbursable tubes to one tube every three months. (Doc. No. 5, Anderson Decl. ¶ 12-14.)

By comparison, Plaintiff submits that the Minnesota Department of Human Services (“DHS”) authorizes a higher reimbursement rate for these same low-profile enteral tubes. In particular, Plaintiff asserts that Medicaid will pay \$138.60 to \$530.29 for items that Medicare will pay only \$35.39, and recognizes that some persons may need up to two tubes per month. (*Id.* ¶ 16.)

II. Procedural History

In March of 2012, the Court heard a motion for a temporary restraining order, in which Plaintiff sought to enjoin Defendants from implementing the Medicare competitive bidding program for all Enteral Nutrients, Equipment and Supplies. (Doc. No. 2.) The Court denied the motion. (Doc. No. 17.) Plaintiff has now brought a second motion for a temporary restraining order, which seeks to enjoin Defendants from awarding or finalizing contracts to providers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (“DMEPOS”) in the Twin Cities competitive bidding area. (Doc. No. 70.) Defendants have represented that they “will not finalize or sign any contracts to supply DMEPOS under the second round of the competitive bidding program prior to March 20, 2013.” (Doc. No. 81.)

Also before the Court is Defendants’ motion to dismiss for lack of subject matter jurisdiction. (Doc. No. 29.) In the alternative, Defendants seek summary judgment based on the administrative record. (*Id.*)

The Court issued a short order on February 26, 2013, granting Defendants’ motion to dismiss and denying the motion for summary judgment and Plaintiff’s temporary restraining order as moot. (Doc. No. 84.) The Court explains its reasoning below.

DISCUSSION

I. Legal Standard

Federal Rule of Civil Procedure 12(b)(1) is the proper vehicle by which to seek dismissal of a claim for lack of federal subject matter jurisdiction. Fed. R. Civ. P. 12(b)(1). A motion to dismiss for lack of subject matter jurisdiction may challenge a

plaintiff's complaint either on its face or on the factual truthfulness of its averments.

Osborn v. United States, 918 F.2d 724, 729 n.6 (8th Cir. 1990). When a defendant brings a facial challenge—a challenge that, even if truthful, the facts alleged in a claim are insufficient to establish jurisdiction—a court reviews the pleadings alone, and the non-moving party receives the same protections as it would defending against a motion brought pursuant to Rule 12(b)(6). *Id.* In a factual challenge to jurisdiction, the court may consider matters outside the pleadings and the non-moving party does not benefit from the safeguards of Rule 12(b)(6). *Id.*

II. Motion to Dismiss

Plaintiff seeks review, pursuant to the Administrative Procedures Act (“APA”), of Defendants’ decision to set a maximum allowable bid for low-profile enteral tubes at \$35.39. Plaintiff alleges that, because the acquisition cost for low-profile enteral tubes is always greater than \$35.39, no bona fide bid for such items is possible under Defendants’ competitive bidding program. (Compl. ¶¶ 6, 91, 132.) Plaintiff further claims that CMS exceeded its enabling legislation by expanding the Medicare competitive bidding process to include dually eligible Medicaid recipients, thereby depriving those individuals of their statutory right to free choice of Medicaid vendor. Plaintiff argues that the competitive bidding program extends beyond the confines of Medicare and thus eliminates Plaintiff’s Medicaid business. All of Plaintiff’s claims, at their core, derive from Plaintiff’s dissatisfaction with the way in which Defendants came to set the Medicare reimbursement amount for low-profile items by failing to consider their therapeutic

advantages and lumping them together with conventional enteral items. (*See id.*

¶¶ 144-48.)

Defendants argue that Plaintiff's claims must be dismissed because the Court lacks subject matter jurisdiction over this dispute. In particular, Defendants contend that Plaintiff's claims are barred by the MMA. *See* 42 U.S.C. § 1395w-3(b)(11).³

In determining whether a statute precludes judicial review, a court "must heed the APA's basic presumption of judicial review," which "will not be cut off unless there is persuasive reason to believe that such was the purpose of Congress." *Tex. Alliance for Home Care Servs. v. Sebilius*, 681 F.3d 402, 408 (D.C. Cir. 2012) (internal quotations omitted). "The presumption favoring judicial review of administrative action," however, "may be overcome by specific language or specific legislative history that is a reliable indicator of congressional intent." *Block v. Cnty. Nutrition Inst.*, 467 U.S. 340, 349 (1984). Here, the APA's presumption of reviewability is overcome by the specific and emphatic statutory language prohibiting judicial review of the competitive bidding process. *See Tex. Alliance*, 681 F.3d at 408.

The MMA provides, in pertinent part:

There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of—

- (A) the establishment of payment amounts under paragraph (5);
- (B) the awarding of contracts under this section;

³ To the extent Plaintiff claims that the MMA is unconstitutional as applied to Plaintiff in violation of Plaintiff's right to due process, the Court concludes this argument lacks merit. *See, e.g., Am. Soc'y of Cataract & Refractive Surgery v. Thompson*, 279 F.3d 447, 454-55 (7th Cir. 2002).

- (C) the designation of competitive acquisition areas under subsection (a)(1)(A) of this section;
- (D) the phased-in implementation under subsection (a)(1)(B) of this section;
- (E) the selection of items and services for competitive acquisition under subsection (a)(2) of this section;
- (F) the bidding structure and number of contractors selected under this section; or
- (G) the implementation of the special rule described in paragraph (10).

42 U.S.C. § 1395w-3(b)(11).

As stated by the D.C. Circuit, “[t]he mandate that there be ‘*no* administrative or judicial review’ under the two cited statutes ‘*or otherwise*’ unequivocally precludes review of the Secretary’s actions addressing the seven aspects of the competitive bidding program enumerated in subsections (b)(11)(A)-(G).” *Tex. Alliance*, 681 F.3d at 409. The statutory language of 42 U.S.C. § 1395w-3(b)(11) expressly immunizes the articulated subjects from review and manifests Congress’s intent to carry out the competitive bidding process “without risk of litigation blocking the execution of the program.” *Id.* “If a no-review provision shields particular types of administrative action, a court may not inquire whether a challenged agency decision is arbitrary, capricious, or procedurally defective, but it must determine whether the challenged agency action is of the sort shielded from review.” *Amgen, Inc. v. Smith*, 357 F.3d 103, 113 (D.C. Cir. 2004).

Here, judicial review of Plaintiff’s claims is expressly precluded by statute. Several of the enumerated subject areas of 42 U.S.C. § 1395w-3(b)(11) encompass the Secretary’s decisions at issue in this lawsuit. Specifically, subsections (A) and (E) prohibit judicial review of “the establishment of payment amounts” and “the selection of items and services for competitive acquisition.” 42 U.S.C. § 1395w-3(b)(11)(A) and (E).

Plaintiff disputes the inclusion of low-profile enteral tubes in the DMEPOS bidding process as well as the maximum bid amount set by Defendants. To the extent Plaintiff seeks to alter the bidding process and the award of contracts, such challenges implicate subsections (B) and (F) of the statute. *Id.* § 1395w-3(b)(11)(B) and (F). Importantly, all of Plaintiff's assertions regarding the Medicare competitive bidding program are derivative of such prohibited challenges. Consequently, Plaintiff's claims are insulated from judicial review.

To the extent Plaintiff contends that Defendants exceeded their enabling legislation and statutory authority, the Court remarks that this issue was a close one. The Court echoes Plaintiff's concern that Defendants' inclusion of dually eligible Medicaid recipients in the Medicare competitive bidding process may, in effect, deprive those individuals of their statutory right to free choice of Medicaid vendor. Still, dually eligible beneficiaries constitute a subset of Medicare beneficiaries, and the Medicare statute does not differentiate between dually eligible beneficiaries and other beneficiaries with respect to covered providers and services.⁴ (*See* Doc. No. 53 at 7-9.) Unfortunately, insofar as DMEPOS are concerned, it appears that Congress may not have contemplated the unjust result of its legislation, with which individuals with developmental and other disabilities

⁴ As articulated by Defendants, because Medicaid is the payer of last resort, Medicare will necessarily absorb some or all of the cost of DMEPOS for dually eligible individuals. (Doc. No. 53 at 2, 9.)

in need of low-profile feeding tubes are now faced. (*See generally* Doc. No. 84.)⁵

Admittedly, the issue of whether Defendants exceeded their enabling legislation and statutory authority was a close call; the Court concludes, however, that the conduct at issue does not rise to such a level.

While the Court finds the allegations in the Complaint highly disconcerting, the Court lacks the subject matter jurisdiction required in order for it to adjudicate Plaintiff's claims on the merits. Defendants' motion to dismiss is thus properly granted.⁶

CONCLUSION

As described in its February 26, 2013 Order, while the Court's decision is supported by law, the Court is deeply concerned about the unjust consequences of its ruling—particularly its effect on those with developmental and other disabilities. The Court reiterates here the clear need for low-profile enteral feeding tubes on the part of those individuals.

⁵ As the Court emphasized in its February 26, 2013 Order, the record “indicates a seeming indifference on the part of Defendants to the fact that individuals with developmental and intellectual disabilities, as well as other disabilities, have a clear need for low profile products because conventional feeding tubes with their long, protruding, external tubing carry a greater risk of accidental removal or dislodgement.” (Doc. No. 84 at 5.)

⁶ Defendants also assert that they are entitled to summary judgment based on the administrative record. Specifically, Defendants contend that the Secretary's decision to include enteral nutrition products in the DMEPOS competitive bidding process was reasonable. Because the Court lacks subject matter jurisdiction to adjudicate Plaintiff's claims, the Court does not reach Defendants' other arguments.

For the same reason, the Court does not reach the merits of Plaintiff's second motion for a temporary restraining order.

ORDER

Based upon the foregoing, **IT IS HEREBY ORDERED** that:

1. Defendants' Motion to Dismiss for Lack of Subject Matter Jurisdiction (Doc. No. [29]) is **GRANTED**.
2. Plaintiff's Verified Complaint for Declaratory Judgment and Injunctive Relief (Doc. No. [1]) is **DISMISSED WITH PREJUDICE**.
3. Defendants' Motion for Summary Judgment Based on the Administrative Record (Doc. No. [29]) is **DENIED AS MOOT**.
4. Plaintiff's Second Motion for Temporary Restraining Order (Doc. No. [70]) is **DENIED AS MOOT**.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: March 19, 2013

s/Donovan W. Frank
DONOVAN W. FRANK
United States District Judge